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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,965	05/24/2001	John Hiscott	A33606-PCTUS	7406

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EXAMINER	
MCKELVEY, TERRY ALAN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,965	HISCOTT ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004 and 12 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-21,26,32 and 34-39* is/are pending in the application.

4a) Of the above claim(s) *3,8-16 and 35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,17,18 and 39* is/are rejected.

7)☒ Claim(s) *6,7,19-21,26,32 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/20/05*.

4)☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *3/3/05*.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

The Office Action mailed 2/3/05 was in error as explained by the attached interview summary and has hereby been withdrawn. Prior to the instant action, the applicant was under no further period for response due to the withdrawn Office Action. The instant Office Action is the official response to the Applicant's responses filed 12/13/04 and 1/12/05.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn

pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/05 has been entered.

Election/Restrictions

Claims 3, 8-16, and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/2/02.

Priority

In the instant case, the application claims priority to foreign application CA 2234588, filed 4/7/1998. A review of this reference shows that there is only priority to claims drawn to phosphorylated IRF-3 or IRF-3 asp/glu mutants. There is no description of modified IRF-7 proteins and no description of more generic IRF proteins because all of the teachings of the reference are exclusively drawn to IRF-3. Thus the elected claims drawn to IRF-7 and claims drawn to generic IRF proteins having the claimed structures/properties, claims 4-7, 17-21, 26, 32, 34, and 39, are accorded a priority date of 4/7/99.

Response to Amendment

The declaration under 37 CFR 1.132 filed 1/12/05 is sufficient to overcome the rejection of claims 5-7 and 39 based upon Lin et al.

Claim Rejections - 35 USC § 102

Claims 5 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoneyama et al (Applicant reference CY, published Feb, 1998). This rejection is maintained for reasons of record set forth in the paper mailed 7/11/04 and repeated below. Applicants' arguments filed 1/12/05 have been fully considered but they are not deemed to be persuasive.

Yoneyama et al teach isolated IRF-3 protein (in SDS gels which reads on IRF-3 that is isolated relative to non-isolated IRF-3) which is phosphorylated following NDV infection (page 1089, columns 1-2), which causes an increase of interferon expression. This reads on the claimed invention because virus infection inherently results in phosphorylation of IRF-3 in the serine or threonine phosphoacceptor site in the carboxy terminus, which causes increased cytokine gene activation by the protein (the inherency is shown by the instant reference and/or the instant application). Thus, the isolated phosphorylated

IRF-3 protein (present in the gels or immunoprecipitated) taught by the reference anticipates the claimed invention.

Response to Arguments

The applicant essentially argues that the mutant IRF-3 taught by the reference are inactive and that the reference does not describe a role for the modification of the actual serine residues (or threonine residues) that are involved in activation of IFN expression. This argument is not persuasive for the instant rejection because Yoneyama et al teach phosphorylated IRF-3, which inherently meets the claim limitations for the reasons described above. The rejection was not based upon the teachings of the substitution mutants, but instead upon the teachings of the isolated IRF-3 protein which is phosphorylated following NDV infection.

The applicant also argues that IRF-3 activation through phosphorylation does not flow as a natural consequence from the reference. This argument is not persuasive because the reference teaches that IRF-3 is phosphorylated from virus infection and that the additional phosphorylation occurs on serine residues (page 1089, top of column 2). The phosphorylated IRF-3 is taught as playing an important role in the virus-inducible primary activation of type I IFN and IFN-

responsive genes (end of the abstract) (which reads on cytokine gene activation). The only thing that is not explicitly taught by the reference is which particular serine residues are phosphorylated, i.e., whether they are in the carboxy terminus domain as claimed. However, whichever serine residues that are phosphorylated is an inherent property of the phosphorylated IRF-3 taught by the reference because even though the particular serine residues are not taught, the ones that are phosphorylated are consistently phosphorylated regardless of whether the reference teaches which ones they are. In other words, the isolated phosphorylated IRF-3 taught by the reference is always biochemically the same; it is just not absolutely known from the reference whether it is the same as claimed. However, based upon its properties, that it is phosphorylated by viral stimulation, that it is phosphorylated at serine residue(s), and that the phosphorylated IRF-3 causes cytokine gene activation, it appears to be a protein that meets the claim limitations. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best,195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of

the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada,15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, IRF-3 activation naturally flows from the reference.

The applicant also argues that it appears that extracts isolated from the reference, aided by hindsight in view of the teachings of the instant application (i.e., phosphorylation of IRF-3 in the serine or threonine phosphoacceptor site in the carboxy terminus) have led the Examiner to incorrectly conclude that the invention is inherently anticipated by the reference. This argument is not persuasive because of the arguments set forth above. The teachings of the instant specification and the teachings of Lin et al (Applicant reference BS of record), which is duplicative of the instant application, merely help shed light on what the chemical makeup of the isolated phosphorylated IRF-3 taught by the instant reference actually is, that the phosphorylation is in the carboxy terminus. The location of the modification is not in the least affected by the hindsight teachings of the instant specification or the teachings of Lin et al because what the makeup of the protein taught by Yoneyama is, simply is. The teachings of the specification and Lin et al and the properties of the phosphorylated IRF-3 protein taught by the reference simply provide a sound basis for believing that

the products of the applicant and the prior art are the same. One of skill in the art would recognize that given all of these teachings that the isolated phosphorylated IRF-3 protein taught by the reference reads on the claimed invention.

Claims 4, 5, 17-18, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Au et al (Applicant reference AC).

Au et al teach a cellular extract comprising IRF-7H (Figure 4 and Experimental Procedures section), which reads on isolated because isolated interpreted as broadly as is reasonable reads on any level of removal of the protein from its natural location in the cell, and which reads on IRF-7 because it is an IRF-7 protein from an alternatively spliced IRF-7 transcript. The IRF-7 was isolated from NDV-infected cells and thus reads on comprising at least one modified serine or threonine phosphoacceptor site, wherein the modification causes cytokine gene activation for the following reasons. As taught by the abstract and at page 29213, column 2, overexpression of IRF-7 results in an activation of IFNA promoter in transient transfection assay and a strong enhancement of virus-mediated activation of this promoter. Because the IFNA promoter is a cytokine promoter, then IRF-7 that is exposed to virus increases

cytokine expression. The reference teaches that no significant enhancement of virus-mediated stimulation of IFNA4 promoter was detected in cells cotransfected with the mutants of IRF-7 that have the carboxyl-terminal parts of the peptide deleted, and that these data indicate that the carboxyl-terminal part of IRF-7 is a target for the virus-mediated modification of IRF-7 (page 29213, column 2). Au et al also teach that the phosphorylation sites (in the serine-rich region of the carboxyl-terminus) seem to be required for the observed synergy between virus and IRF-7H in the activation of the IFNA promoter, which was observed only with the full-length IRF-7H but not with its carboxyl-terminal deletion mutants (page 29216, bottom of column 2). These teachings show that the isolated IRF-7H from virus infected cells taught by Au et al is IRF-7 that has phosphorylation modifications in the carboxyl-terminus and thus reads on the claimed inventions.

Regarding which serine residues are modified, based upon the location of the serines, and the teachings of Au et al, Lin et al (described in the arguments above) and the instant specification, it appears that the phosphorylation of IRF-7H is inherently at Ser-477 and/or Ser-479.

Allowable Subject Matter

Claims 6, 7, 19-21, 26, 32, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's

Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to

about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 27, 2005